



## Commercial/Healthcare Exchange PA Criteria

*Effective: November 2016*

**Prior Authorization:** Soliqua

**Products Affected:** Soliqua (insulin glargine and lixisenatide) 100/33: Insulin glargine 100 units and lixisenatide 33 mcg per mL Subcutaneous Solution Pen-injector

**Medication Description:** Insulin glargine; lixisenatide is a subcutaneous injection containing a combination of basal insulin (insulin glargine) and a glucagon-like peptide-1 receptor agonist (GLP-1 RA) (lixisenatide). The combination is used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM). The combination of allows for administration once-daily at the same time each day given within the hour before the first meal of the day. Insulin glargine gives a flat and stable effect on blood glucose throughout the day; lixisenatide stimulates insulin secretion and lowers inappropriately high glucagon secretion in a glucose-dependent manner.

**Covered Uses:** Soliqua 100/33 is a combination of insulin glargine and lixisenatide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

**Exclusion Criteria:**

1. Hypoglycemia
2. Patients with a history of pancreatitis
3. Patients with a history of gastroparesis
4. Treatment of patients with type 1 diabetes mellitus
5. Treatment of patients with diabetic ketoacidosis

**Required Medical Information:**

1. Diagnosis
2. Past medications tried/failed

**Age Restrictions:** 18 years of age and older

**Prescriber Restrictions:** Prescribed by, or in consultation with, an endocrinologist, or a physician who focuses in the treatment of diabetes and/or disorders of the endocrine system

**Coverage Duration:** 12 months

**Other Criteria:** Approve if the patient has met all of the following criteria:

- A. The patient has a diagnosis of type 2 diabetes mellitus; AND
- B. The patient's A1C is > 7%; AND
- C. The patient will not be using Soliqua in combination with any other product containing a GLP-1 receptor agonist; AND
- D. The patient has documented trial, failure or contraindication to Xultophy

Last Res.11.22.2019



Confidential Information

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**References:**

1. Product Information: SOLIQUA(R) 100/33 subcutaneous injection, insulin glargine lixisenatide subcutaneous injection. sanofi-aventis US LLC (per FDA), Bridgewater, NJ, 2019.

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	11/2016
2	Update	<p>Adopted EH Template;            Added Rybelsus as preferred GLP1;            Added criteria: The patient will not be using Soliqua in combination with any other product containing a GLP-1 receptor agonist; added exclusions to match FDA label            Removed criteria requiring trials of meds other than Xultophy</p>	All	11/22/2019

